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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,716	05/28/2008	Suku Thambar	18461-65814	9258

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BINGHAM MCHALE LLP
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INDIANAPOLIS, IN 46204-4900

EXAMINER

MASHACK, MARK F

ART UNIT	PAPER NUMBER
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3773

NOTIFICATION DATE	DELIVERY MODE
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09/29/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/598,716	Applicant(s) THAMBAR ET AL.	
	Examiner MARK MASHACK	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-18, 40-45 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-39, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/13/2008, 7/23/2008, 1/14/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to a communication dated 5/6/2009. Claims 19-39 and 46-47 are pending.

Election/Restrictions

1. Claims 1-18, 40-45, and 48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/6/2009.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 19-24, 27-35, 38-39** are rejected under 35 U.S.C. 102(b) as being anticipated by **Bailey et al. ("Bailey" US 6,458,153)**.

Bailey discloses a percutaneous heart valve comprising: a valve body **12** ; one or more flexible valve elements **26**; said valve body tapers from one end to a second end such that one end is sized to pass through a valve orifice and a second end being sized not to pass through the valve orifice (FIG 1-5, 6, 12, 13-17). The valve body comprises a superelastic memory material (Column 5, Lines 33-40). Sub-frame members with general deltoids/rhombus shapes with acute angle vertices at said first and second ends and obtuse angle vertices between can be appreciated (e.g. members

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of element **16** and **22**). The sub-frame members are joined at the vertices by diagonal elements (e.g. members of element **20**) which secures the valve elements **26** (FIG 2). The prosthesis is a mitral valve prosthesis (Column 9, Line 61, - Column 10, Line 14). The sub-frame members are joined at respective oblique-angled vertices (FIG 1). The flange elements **22** comprise prongs. An elongate guide element **222** is detachable attached to the valve and is capable of extending beyond catheter **210** (Column 13, Lines 15-21).

4. **Claims 19-24, 27-28, 30-35, 38** are rejected under 35 U.S.C. 102(b) as being anticipated by **Seguin (WO 03/003949 translated into US 2005/0043790)**.

Seguin discloses a valve body having a valve body first end, a valve body second end, a passage; one or more flexible valve elements **4**; a plurality of prongs **15**; wherein said valve body tapers such that one end is sized to pass through an orifice and one end sized not to pass. The valve is intended to be delivered via a collapsed configuration by a catheter (Paragraph 50) and is intended to be made a superelastic material (Paragraph 48). The valve body comprises at least three rhombus-shaped sub-frame members (cells comprising elements **10** and **12**) and prongs **15**.

5. **Claims 19-20, 22-26** are rejected under 35 U.S.C. 102(b) as being anticipated by **Cribier et al. ("Cribier" US 2003/0014104)**.

Cribier discloses a percutaneous heart valve prosthesis comprising: a valve body **10** which tapers from one end to the second end to maintain the valve in position (Paragraph 41); one or more flexible valve elements **14**; the valve body comprises at

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least three valve body sub-frame members having the shape of a deltoid or rhombus and joined at the oblique vertices (FIG 3b). The subframe member further comprise collapsible diagonal member **17** extending between said oblique-angled vertices secured to said valve elements (Paragraph 93).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 30-38** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Cribier** in view of **Seguin et al. ("Seguin" US 2004/0093060)**.

Cribier discloses all of the claimed limitations except for a plurality of prongs spaced. However, **Seguin** teaches of a similar valve prosthesis comprising a plurality of prongs (Paragraph 10). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of **Cribier** with prongs in order to ensure proper positioning (Paragraph 7).

8. **Claims 46-47** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bailey** in view of **Goar et al. ("Goar" US 2004/0039442)**.

Bailey discloses of the device of Claims 19 and 30 and a method of treating a failed or failing mitral valve (FIG 12A-B and Column 11, Lines 13-27). In another

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embodiment, **Bailey** explicitly discloses advancing the catheter **503** past the valve being treated and wedging the valve body into the orifice in order to dilate the valve orifice (FIG 20 and Column 14, Lines 6-55). The valve body is partially advanced through the catheter for deployment prior to the wedging (Column 14, Lines 19-28); however, the claim language, as written, does not require that chronological aspect of the sequence. It would have been obvious or inherent to advance the catheter into the left atrium while treating the mitral valve in order to perform the valvuloplasty step. **Bailey** does not explicitly disclose of how the catheter would be positioned in the left atrium. However, **Goar** teaches of a method of accessing the mitral valve through the right and left atrium via a trans-septal puncture (FIG 8). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of **Bailey** with the trans-septal puncture to facilitate the positioning of the catheter in the left atrium.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773